INJECTION CARTRIDGE FILLING APPARATUS

Cross-Reference to Related Application

[0001] This application claims the benefit of U.S. provisional patent application Serial No. 60/431,895 filed December 9, 2002.

Background of the Invention

Field of the Invention

[0002] The present invention deals with a handheld cartridge filling apparatus for filling the cartridge with vaccines or other fluids, and in particular to hand-operated cartridge filling apparatus for use with needle-free ampules or cartridges and the associated filling station.

Description of Prior Art

[0003] The specification of U.S. Patent Publication US 2003/0040715A1, filed August 20, 2002, and corresponding PCT Publication WO 03/015846 A2, filed August 21, 2002, herein incorporated by reference, describes several methods for filling ampules or cartridges prior to their use with a needle-free injection system. In particular, the foregoing earlier publications illustrate a filling station that uses a transfer syringe which first extracts vaccine or other medication from the vial supplied by the manufacturer. The transfer syringe is then placed into a described filling station and the vaccine therein is progressively transferred from the syringe into the orifice, or distal end of the empty ampules or cartridges. This filling procedure is accomplished with a simple repetitive motion of a lever which incrementally advances the syringe plunger to move the vaccine out of the syringe and into the cartridge. Also mentioned in the preceding patent publications is the possibility of filling through the orifice end of the cartridge by pressurizing the vial to fill the cartridge without the use of a transfer syringe. It was stated in the specification of the foregoing publications, that "the main difficulty in using the vial without first transferring to the syringe, comes in

the valving required to control flow of air into the vial and flow of injectate out of the vial". However, the simplified and inexpensive method of valving and pressure control as discussed in this disclosure is applied to a hand-held apparatus that houses the vial directly, and is then used to fill the ampules through the orifice end. During the development, it was realized that the handheld apparatus for transferring vaccine can also be used in the filling station in place of a syringe. With regard to vaccine transfer with the handheld device, neither the valving or filling station option was illustrated in the earlier application.

Summary of the Invention

[0004] An object of the present invention is to provide apparatus for filling one or more cartridges with vaccines or other fluids for use with injection or other devices.

[0005] Another object is to provide apparatus for discharging fluid from a container having a septum over its discharge end and for filling one or more cartridges with the fluid.

[0006] A further object is to provide apparatus for severing the septum of a vial or other container to release fluid held therein into an optional metering station to minimize lost fluid at the end of its use.

[0007] A still additional object is to provide apparatus for holding a cartridge having an openable, flexible, protective cover for maintaining sterility before, during, and after filling, and to fill the cartridge with a desired fluid.

[0008] It is a further object of the invention to provide apparatus for opening the septum of a container to discharge fluid therefrom, to optionally meter the discharged fluid, and to fill one or more cartridges with the fluid.

[0009] A still additional object of the present invention is to provide a hand operated, portable apparatus for discharging fluid from a container, metering the discharged fluid, and filling one or more cartridges with the fluid.

[0010] A yet further object of the invention is to provide a cartridge filling apparatus for use with cartridges having an orifice, walls defining the interior of the cartridge, and a piston disposed in the interior of the cartridge and movable from a position near the orifice end away from the orifice to define the maximum capacity of the cartridge, where the cartridge length limits the maximum amount of movement of the piston and the maximum capacity of the cartridge.

[0011] Still another object of the invention is to provide a variable size piston stop to fill the cartridge to selected amounts that are less than its maximum capacity.

[0012] It is yet still a further object of the invention to provide apparatus for opening the septum of a container holding fluid.

[0013] Still a further object is to provide an improved piercing device in apparatus for discharging fluid from a container whose discharge orifice is covered with a septum.

[0014] Another object of the present invention is to provide means for delivering air to a container having fluid discharged therefrom through a severed septum which had covered the discharge orifice.

[0015] Another object is to provide an optional metering station for apparatus for discharging fluid from a container.

[0016] An additional object is to provide a fluid flow system for transferring fluid from a container whose fluid contents have been discharged to an optional metering station for use in a cartridge filling apparatus.

[0017] A more specific object is to provide apparatus for removing fluid from a vial or other container holding a desired fluid and fill health care cartridges in optional metered amounts with the fluid either one at a time as in a hospital, doctor's office, research facility or at some site, or to fill a multitude of cartridges for use in a magazine for mass inoculation purposes.

[0018] Another particular object is to provide the apparatus as set forth in the preceding paragraph for use with cartridges having an orifice at one end, walls defining an interior, and a piston movable in the interior away from the orifice as fluid is transferred to the cartridge, the final piston of the cartridge determining its capacity.

[0019] Another specific object of the invention is to provide a hand operated apparatus for filling cartridges as set forth in the preceding paragraph which is compact, easy and efficient in use, inexpensive and efficient and long lasting in operation.

[0020] These and other objects will be apparent from the description to follow and from the appended claims.

[0021] The invention includes in one respect apparatus for opening the septum of a vial or other container upon the insertion of the container into the apparatus. The apparatus in this respect is a housing having a septum severing device in the form of a spike for piercing the septum when the inverted container is inserted into the apparatus. The spike includes a conduit for discharging fluid from the container and has a one-way valve for controlling the flow from the container. The spike further has another conduit through which atmospheric air can enter the container, also having a one-way valve.

[0022] The invention includes in another respect a discharge device including an optional metering structure having a chamber with a cavity of variable size to receive

desired amounts of fluid for transfer to the cartridge. A tubular member (which is preferably cylindrical but could be of any shape) conveys the fluid from the metering structure to the cartridge. A tubular member has a one-way valve for preventing the leakage of fluid when there is no cartridge positioned to receive the fluid.

[0023] According to one preferred embodiment of the invention, the discharge device is in the form of a cartridge interface device or cartridge receiver which has both a cartridge positioning device for positioning a cartridge to receive the fluid, and walls for cooperating with the housing to define an optional metering station. A spring structure biases the housing to cause the cavity of the metering station to assume its largest size. A tubular rod from the metering station defines a path for fluid to flow from the metering station to the cartridge.

[0024] In another preferred embodiment of the invention, the discharge device includes spring biased walls which cooperate with walls from the housing to define an optional metering structure. A cartridge positioning device locates a cartridge between the walls, and the amount the cartridge extends between the walls when force is applied to the housing to move the housing and metering structure over the cartridge, determines the size of the metering station. In both of the preferred embodiments, the spring structure returns the unit to its initial position after the cartridge has been filled.

Brief Description of the Drawings

[0025] The invention may take physical form in certain parts and arrangement of parts, a preferred embodiment of which will be described in detail in the specification and illustrated in the accompanying drawings which form a part hereof, and wherein:

[0026] FIG. 1 is a front perspective view of a filling apparatus;

[0027] FIG. 2A is a perspective cross section of the filling apparatus of FIG. 1 showing positioning of the vial when inserted for transfer of the fluid;

[0028] FIG. 2B is an enlarged schematic cross section of a simplified series of elements for the inner structure of FIG 2A showing the, spring, valves, and flow path for the fluid into the cartridge and the venting path for air into the vial;

[0029] FIG. 3 is also an enlarged schematic of a simplified cross section of another embodiment of the filling apparatus showing a reversal of the forces related to the air and fluid flow from that of FIG. 2B;

[0030] FIG. 4A is a perspective view of a filling station prior to insertion of the filling apparatus shown in FIG 2;

[0031] FIG. 4B is a perspective view of a filling station with the medication vial inserted in the filling apparatus;

[0032] FIG. 4C is a perspective view of a filling station with the transfer syringe inserted in the filling apparatus; and

[0033] FIG. 5 is a disposable, sterile magazine, illustrating the structure for holding 30 cartridges ready for the sterile filling procedure as shown in either of Figures 4B or 4C.

Detailed Description of the Preferred Embodiment

[0034] Referring now to the drawings wherein the showings are for the purpose of illustrating the preferred embodiment of the invention only, and not for the purpose of limiting same, the attached figures illustrate two embodiments of a handheld ampule or cartridge filling apparatus discussed above, or alternatively, for insertion into a filling station as described below for FIG. 4A and 4B. FIG. 1, FIG. 2A and FIG. 2B are enlarged and do not necessarily resemble actual dimensions. (The term "fill" refers to the amount of fluid transferred to a cartridge, which can be any amount up to

the maximum capacity.) For example, spike 23 and 23' (described below) are less than one-eighths (1/8) inch in diameter and take very little space when inserted into the septum end of a vial 12 (also described below). Likewise, channels 28 and 30 (described later) inside septum spike 23 are less than 1 mm. in diameter. However, the figures are used to clearly illustrate and describe the first embodiment of the invention. FIGS. 1, 2A, 2B and 3 disclose a cartridge filling apparatus 10, which houses a vial, bottle or similar vessel 12 for holding vaccine or the like when it is inserted into an opening 14 in a flared open housing or handpiece 11. Handpiece or housing 11 is a hollow, preferably truncated rounded cone-like structure. Housing 11 includes a shoulder 13 for receiving a rim 15 of the septum end 17 of vial 12, which rim 15 abuts against the shoulder. Housing 11 has an interior diameter dimensioned to receive the body of the largest vial 12 anticipated, but smaller vials can also be used. A bored collar 19 extends across a relatively large bored neck 21 of housing 11. A wall 25 extends through a severing device, such as a bored spike 23, and forms with spike 23 two channels or conduits 28 and 30 whose paths are fully isolated from each other. A vaccine compartment 31 is formed between collar 19 and an open end 27 of housing 11.

[0035] At insertion of vial 12, septum end 17 of vial 12 is punctured by piercing bottle spike 23. Channel 28 includes a one-way valve 32 for discharging vaccine (or other fluid) out of vial 12 and into an optional metering station such as a metered compartment or internal vaccine chamber 31 whose purpose is to limit the amount of fluid lost at the end of its use, and the second channel or conduit 30 has a one-way valve 34 for admitting atmospheric air into vial 12 as the vaccine (or other fluid) is extracted. While both one-way valves 32 and 34 are shown as conventional and inexpensive duckbill valves, other one-way valve types such as an umbrella flap or

ball and socket valves will work as well. Metering station 31 is thus a collapsible chamber having a relative large cavity when in its open state, and a relatively small cavity when in its closed state (as discussed herein).

[0036] Apparatus 10 is used for filling cartridges or ampules 18 as discussed below. Apparatus 10 further includes a cartridge interface device, a cartridge receiver or nosepiece 33. Receiver or interface device 33 has an outer cylindrical wall 39 and an inner tubular cylindrical wall or rod 35 to define between them a cylindrical chamber 36 closed at its distal end by a cylindrical ring 38. Neck 21 of housing 11 extends into chamber 36, and one or more springs or other biasing device 40 supports housing 11 and vial 12 (if disposed in housing 11) to form a spring valve subassembly 42. Rod 35 has a longitudinal bore 44. A seal 46 prevents the flow of liquid between neck 21 and rod 35 as discussed below. A low pressure cracking valve 48, also discussed below, extends across bore 44 of rod 35. The term "discharge device" refers to the part of the interface to form the optional metering station and the member defining the fluid flow path to the cartridge.

[0037] Cartridge receiver 33 further includes a receptacle or receiver end 49 for interfacing with the filling end of a received cartridge 18. A seal 50 prevents the leakage of liquid from the space between received cartridge 18 and the wall-defining receptacle 49.

[0038] Cartridges 18 each have a generally cylindrical inside chamber. A longitudinally movable cartridge piston 52 is disposed in the chamber. Cartridges 18 each have a cylindrical base 54 and open entrance end or orifice 56.

[0039] A platform 58 is provided for receiving base 54 of each of cartridges 18 and has a protrusion or appendage 60 for extending into the space in base 54 of cartridge 18. Piston 52 forms the movable bottom of cartridge 18. As explained later, cartridge

18 usually has an openable, flexible sheet across its orifice as interface device 33 is moved down over the end of cartridge 18, it opens the sheet to provide and maintain a completely sterile access to the orifice, before, during, and after the filling process.

[0040] In its operation, cartridge receiver 33 of apparatus 10 is placed over the orifice 56 interface of cartridges 18. The entire housing 11 is then forced downward as shown by direction arrow 20. This action forces rod 35 upward against spring valve subassembly 42. As rod 35 is forced upward into internal vaccine compartment 31, compartment or chamber 31 decreases in size, and the vaccine (or other fluid) contained therein is forced downward through bore 44 in rod 35 and into orifice 56 of cartridge 18 to discharge the vaccine (or fluid) into cartridge 18. This motion forces the cartridge piston 52 to the proximal end of cartridge 18 as described above. Low cracking pressure valve 48 prevents leakage when no cartridge at all is located in a receiver end 49 which positions or registers the cartridge to receive the vaccine (or fluid). Appendage 60 on support platform 58 stops piston 52 when cartridges 18 are filled to the selected amount. Appendage 60 can be supplied in a variety of sizes to vary the dose cartridges 18 are capable of taking.

[0041] When the force movable in direction of force vector 20 is removed from housing 11, biasing device 40 will return rod 35 to its extended position. This action provides a vacuum force in chamber 31 and a new supply of fluid is drawn into chamber 31 through one-way valve 32 from vial 12. The removal of fluid from vial 12 causes a slight vacuum therein; therefore, atmospheric one-way valve 34 in the air vent path of spike 23 admits enough atmospheric air to relieve the vacuum. This action/reaction assures easy withdrawal of vaccine for the next cycle.

[0042] FIG. 3 is a second embodiment of the handheld concept disclosed herein, again enlarged, and with similar functions having the same numbers as those in Figure

2A and FIG. 2B with prime superscripts. While the force vectors for the transfer of fluid and airflow are reversed from that of FIGS. 2A and 2B, negative pressure fills chambers 31 in FIG. 2B. Positive pressure fills chamber 31 in FIG. 3. This embodiment is also capable of being used with a filling station apparatus similar to that shown and described below with respect to in Figure 4.

[0043] A cartridge filling apparatus 10' of FIG. 3 includes a handpiece or housing 11' having walls for receiving vial 12. Housing 11' is as before a generally truncated, flared core-like structure with an opening 14'. Housing 11' has a bored collar 19' against which rim 15 of septum 17 of vial 12 can abut. A bored collar 19' has extending therefrom bored bottle spike 23' with piercing point 22'. Wall 25' cooperates with spike 23' to define channels 28' and 30'. One-way valve 34' is located in channel 30' for admitting air into vial 12 and one-way valve 32' is disposed in channel 28' for discharging vaccine (or other fluid) from vial 12. A one-way air valve 70 extends through neck 21'. A wall or post 72 depends from wall or center post 25' of septum spike 23 to fully isolate the air side from the fluid side of bored collar 19', and has at its end a cylindrical structure 74 with a cylindrical wall 76 and a cap 78.

[0044] Housing 11' has an enlarged, open cylindrical portion 80 having within it a cylindrical wall 82 which cooperates with wall 76 also within portion 80 and on the interior thereof to define a cylindrical compartment 84. Low pressure cracking valve 48' extends between walls 76 and 82 for admitting fluid from vial 12 into metered fluid compartment 84 and then into the orifice end of cartridge 18. The bottom portion of cylindrical compartment 84, just above the point where it interfaces with cartridge 18, has a door structure that will open as cartridge 18 advances into compartment 84 while filling, and closes when cartridge 18 is pulled out, and will prevent the leakage of fluid (vaccine) in the absence of cartridge 18. In this

embodiment, the discharge device refers to cartridge 18 and the member defining the fluid flow path to the cartridge.

[0045] A cylindrical structure 86 extends from platform 58' for reception into open end 88 of air compartment 85. An air seal 90 is between the outer wall of cylinder 86 and the walls defining compartment 85. A fluid seal 92 is located between walls 76 and 82 for engaging cartridge 18 when it extends into compartment 84. Cartridge 18 has piston 52' as discussed earlier. Platform 58' has protrusion 60' for entering cartridges 18. A compressible spring assembly 94 extends between cylindrical structure 74 and platform 58'.

[0046] In operating the FIG. 3 embodiment, force vector 20 pushes vial 12 and housing 11 downward against stationary platform 58' containing cylindrical member 86 and cylindrical cartridges 18. Entrance of cylindrical member 86 into air-containing compartment 85 forces air into vial 12' through one-way valve 34'. The resulting pressure in vial 12 forces vaccine through exit one-way valve 32' and into the orifice, or distal end 56, of cartridge 18. Pushing vial 12' in the downward direction also compresses spring 94, and therefore removal of force vector 20' from vial 12' allows spring 94 to push cylindrical structure 74 and housing 11' away from cylindrical member 86 whose function is that of a pump. Removal of cylinder 86 creates a vacuum in compartment 85 and therefore permits the entrance of atmospheric air into compartment 85 through one-way valve 70 in preparation for the next cycle. Conversely, filling apparatus 10' of FIG. 3 can also be used with vial 12' and housing 11' held stationary, and cylinder 86 and cartridges 18 are pushed toward vial 12' and housing 11' to provoke the filling process. As explained earlier, seal 90 prevents the leakage of air when housing 11' and compartment 85 move over cylinder 86, and seal 92 prevents leakage of fluid when the housing moves over cartridges 18.

As explained later, the openable, flexible cover on cartridge 18 is opened as the lower portions of walls 82 and 76 approach the orifice end of cartridge 18.

[0047] FIG. 4A shows a filling station 80 before any of the handheld filling apparatus of FIG. 1, FIG. 2, or FIG. 3 has been inserted for the filling of cartridges contained in a magazine structure described for FIG. 5 below. Filling station 80 includes a handle assembly 82 having an upper jaw 87, a lower jaw 86 and a jaw-connecting column 88. Upper jaw 87 has a vertically movable flange 90 with forked support arms 92 defining a gripping portion 94 for holding an intermediate portion of an inverted manual cartridge-filling apparatus such as apparatus 10 or 10'. Lower jaw 86 includes an upwardly curved flange 96 having forked gripping arms 98 defining a gripping portion 100 for gripping the lower portion of an inverted cartridge-filling apparatus 10 or 10'. Upper flange 90 and lower flange 96 move together against the bias of a compression spring mechanism 99, and in doing so, advance the entire housing 11 or 11' toward the cartridge orifice for filling, and after contact is made, continues to move housing 11 or 11' forward against the pump spring in apparatus 10 or 10' to execute the filling of cartridge 18.

[0048] Filling station 80 includes a platform 102 having an extension 104 for supporting handle assembly 82 with flanges 90 and 96. Located on platform 102 is a sliding magazine holder 106. In its operation, filling station 80 of FIG. 4 will accept filling apparatus 10 or 10' in jaw structure 84, 86. Handle 82 of filling station 80 is forced downwardly against spring mechanism 99. This downward motion provides force vector 20 as described above for the handheld operation of filling apparatuses 10 and 10' described with respect to FIG. 1, FIG. 2A, FIG. 2B and FIG. 3.

[0049] FIG. 4B shows filling station 80 housing the vial direct apparatus described with respect to FIG. 1, FIGS. 2A and 2B, and FIG. 4C shows the same filling station

housing the transfer syringe for filling the cartridge as described in U.S. Publication 2003/0040715A1. However, in the case of FIG. 4C, the negative pressure described for the vial-direct apparatus of FIG. 4B now serves to pull a plunger rod 116 downward as fluid is pulled from syringe 118.

[0050] The filling station described in U.S. Patent Publication US 2003/0040715A1 includes a disposable magazine similar in nature to that shown herein in FIG. 5. This magazine concept has the features listed below and includes a laminated cover 110 to protect the orifice end of the cartridges 18 therein providing for complete sterility before, during, and after filling. The disposable magazine can be made of low-cost plastic and can have the orifice end of the cartridges installed via friction fit in mating depressions 112. Laminated cover 110 can be made of foil and Mylar to protect the orifice, provide for efficient sterilization, packaging and shipping of the magazine and its cartridges. Cover 110 can be applied over the filling access ports, i.e., orifices 56, but need not be removed to fill the cartridges. Cover 110 thus includes a flat section 111 and integral protrusions 113 for receiving the upper parts of cartridges 18. The lamination is designed to yield with the application of pressure from the forwardmost end of cylindrical chamber 36 comprised of distal end cylindrical ring 38 when it advances to make access to the orifice during filling. At this time the lamination of cover 110 will be forced to the open position with the first advance of the outer ring 38 on receiver 36 of apparatus 10 or the lower portions of walls 76 and 82 of apparatus 10', after which the nozzle that transfers the vaccine will advance through outer ring 36 or lower portions of walls 76 and 82, make contact with cartridges 18, and filling takes place through orifice 56 or 56'. Since neither the filling nozzle nor orifice 56 or 56' makes any contact with outside surfaces, the procedure is free from the risk of contamination. The lamination consists of a foil top layer that provides a protective

seal for the space in front of the orifice. Depression in the foil after filling provides a visual indication that a cartridge has been filled. The second layer 112 of the lamination is made from a material such as Mylar that can spring back to its original position and reseal the surface after penetration from the filling nozzle is removed. Layer 112 is pierced with an "X" pattern 114, coincident with each of the filling access openings in the disposable magazine. When the filling interface is pressed through the foil layer, "X" pattern 114 opens downward and outward from the center to allow the filling interface to seal against the cartridge nozzle. When the filling interface is withdrawn, the "X" pattern returns to its original position, thus protecting the orifice from external contamination as described above. There could be a third, resealable top layer that can be pulled away to expose the foil and replaced after filling to further enhance protection.

[0051] The invention has been described with particular emphasis on the preferred embodiment. It should be appreciated that these embodiments are described for purposes of illustration only, and that numerous alterations and modifications may be practiced by those skilled in the art without departing from the spirit and scope of the invention, it is intended that all such modifications and alterations be included insofar as they come within the scope of the invention or the equivalents thereof.